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CAUSE NO.

STATE OF TEXAS,

Plaintiff

VS.

VALERIE SAXION, INC. and
VALERIE SAXION, individually,

Defendants

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IN THE DISTRICT COURT OF

TARRANT COUNTY, TEXAS

348th JUDICIAL DISTRICT

2011 MAR 23 AM 9:25
JAMES A. HILL
CLERK

PLAINTIFF'S ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, the STATE OF TEXAS, plaintiff, acting by and through Attorney General Greg Abbott, and files this its Original Petition against VALERIE SAXION, INC. and VALERIE SAXION, individually (hereinafter "Defendants"), and would respectfully show the court the following:

DISCOVERY CONTROL PLAN

1. Discovery is intended to be conducted under Level 2 of Texas Civil Procedure Rule 190.

AUTHORITY

2. This action is brought by Attorney General Greg Abbott, through his Consumer Protection and Public Health Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §431.047 and §431.0585 of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. §431.001 *et seq.* ("TFDCA"). Section

431.047 of the TFDCA authorizes the Attorney General to seek injunctive relief under certain circumstances and recover any costs and attorney fees incurred in obtaining that relief. Section 431.0585 authorizes the Attorney General, after a referral from the Commissioner, to seek civil penalties in favor of the State for any violation of § 431.021 of the TFDCA.

3. This action is brought by Attorney General Greg Abbott, through his Consumer Protection and Public Health Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §17.47 of the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.* ("DTPA"), upon the grounds that Defendants have engaged in false, misleading, or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by §§17.46(a) and (b) of the DTPA.

PARTY DEFENDANTS

4 Defendant VALERIE SAXION, INC. is a Texas corporation which may be served with process by serving its director Valerie Saxion at its principal place of business at 3800 Sandshell, Suite 130, Fort Worth, Texas 76137 or by serving its registered agent Gregory G. Jones c/o Law Firm of Gregory G. Jones, P.C., at 630 East Southlake Boulevard, Suite 110, Southlake, Texas 76092.

5. Defendant VALERIE SAXION, a resident of Texas, is the owner, president, and director of VALERIE SAXION, INC. and may be served at her place of residence at 1323 Briar Ridge Drive, Keller, Texas 76248-8376 or, in the alternative, at her place of business at 3800 Sandshell, Suite 130, Fort Worth, Texas 76137.

VENUE

6. Venue of this action lies in Tarrant County on the basis of §17.47(b) of the DTPA by virtue of the fact that Defendants have their principal place of business in Tarrant County.

7. Venue of this action lies in Tarrant County on the basis of §431.047(c) and §431.0585(d) of the TFDCA by virtue of the fact that violations and threat of violations occurred in Tarrant County.

PUBLIC INTEREST

8. By reason of the institution and operation of the unlawful practices set forth herein, Defendants have caused and could continue to cause adverse effects to legitimate business enterprise which conducts its trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the State of Texas believes and is of the opinion that these proceedings are in the public interest.

TRADE AND COMMERCE

9. Defendants VALERIE SAXION, INC. and VALERIE SAXION, individually, are engaged in trade and commerce, as that term is defined by §17.45(6) of the DTPA, in that Defendants are or were engaged in the business of offering for sale, selling, and distributing tangible goods in Texas.

NOTICE BEFORE SUIT

10. All conditions precedent to Plaintiff's claim for relief have been performed or have occurred. Pursuant to §17.47(a) of the Deceptive Trade Practices Act, contact has been made with the Defendants VALERIE SAXION, INC. and VALERIE SAXION, individually, herein to inform Defendants in general of the unlawful conduct alleged herein, by letters mailed

by certified mail, return receipt requested.

ACTS OF AGENTS

11. Whenever it is alleged in this petition that Defendants did any act or thing, it is meant that Defendants performed or participated in such act or thing or that such act was performed by the officers, agents or employees of said Defendants, and in each instance, the officers, agents or employees of said Defendants that were then authorized to act did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of the Defendants.

NATURE OF DEFENDANTS' CONDUCT

12. Defendant VALERIE SAXION, INC. operates a business in which it offers for sale, sells, and distributes tangible goods, including dietary supplements, skin care products, and books to customers via telephone and the website www.valeriesaxion.com.

13. Defendant VALERIE SAXION is the owner and serves as the president and director of VALERIE SAXION, INC. As such, Defendant VALERIE SAXION has the responsibility for the overall management and oversight of the company, including compliance with all state and federal statutes regulating VALERIE SAXION, INC. She also has the responsibility of supervising other officers, directors, and employees of the corporation. As a result, Defendant VALERIE SAXION directs and has personal knowledge of the day-to-day activities of the company.

14. Defendant VALERIE SAXION promotes VALERIE SAXION, INC.'S products through a television show entitled "Alternative Health."

15. Defendant VALERIE SAXION promotes herself as a naturopathic doctor (N.D.),

but Texas does not recognize naturopaths. Additionally, on the website www.valeriesaxion.com, Defendant VALERIE SAXION stated that she received her doctorate in naturopathy from Clayton College. Clayton College of Natural Health is on the Texas Higher Education Coordinating Board's list of institutions whose degrees are illegal to use in Texas.¹ According to the list, Clayton College does not have accreditation from an accreditor recognized by the Coordinating Board. Any use of terms like "Doctor" or "Dr." in connection with Defendant VALERIE SAXION is false, misleading, or deceptive under the DTPA. Additionally, any use of terms like "Doctor" or "Dr." with Defendant VALERIE SAXION'S name on the label, in labeling, or in advertising in Texas constitutes false advertising under both the TFDCA and the DTPA.

Inspections of May 13, 2009, February 18, 2010, November 19, 2010 and June 3, 2011

16. On May 13, 2009 and, again, on February 18, 2010, November 19, 2010, and June 3, 2011, the Texas Department of State Health Services ("TDSHS") inspected Defendants' business premises at 3800 Sandshell, Suite 130, Fort Worth, Texas. During one or more of the inspections, TDSHS made the determinations found in paragraphs 17 through 25 below.

17. TDSHS determined that Defendants make explicit and implicit statements claiming that their dietary supplements can diagnose, mitigate, treat, cure, or prevent disease. As an example, some of the claims made by Defendants for their products include, but are not limited to, the following:

A. "CLA has been shown to have strong anti-cancer properties. Especially in

¹The list of institutions can be found at <http://www.thecb.state.tx.us/apps/ConsumerInfo/NoTX.cfm> last checked on August 26, 2011.

inhibiting breast and prostate tumors as well as colorectal, stomach and skin cancer, including melanoma....CLA even lowered cancer cell growth. CLA is an excellent inhibitor of tumor growth."

B. "I told him about chelation suppositories and how effective this treatment was for my heart, blood pressure, diabetes, body fungus, severe arthritis, crippling hip/leg pain, relief from bulging discs in my back along with pinched nerves, and relief from ringing ears."

C. "The primary therapeutic applications for 5-HTP is (sic) low serotonin states. Conditions associated with low serotonin levels helped by 5-HTP are: Depression, Obesity, Carbohydrate craving, Bulimia, Insomnia, Narcolepsy, Sleep apnea, Migraine headaches, Tension headaches, Chronic daily headaches, Premenstrual syndrome, and Fibromyalgia."

D. "A partial list of bacteria/viruses tested and neutralized with Colloidal Silver in the laboratory were: Lyme disease, Herpes, Legionnaire, Staphylococcus, Aureus (sic), Salmonella, Choleraesuis, Streptococci, Warts, Pseudomonas, Aeruginosa, Neisseria, Gonorrhea, Gardnerella Vaginalis, Gangrene and Candida. It is great for BURNS and CUTS, too."

E. JC360 Graviola: "Derived from the Soursop tree, research indicates this is a nutrient that can help the body fight inferior cells, making it a great addition to a complete cancer program. It has many other uses, including fever, influenza...."

F. Ashwagandha (*Withania somnifera*): "The result is a botanical that relaxes the mind, rejuvenates the body, and increases resistance to stress*....Some

researchers speculate that the herb may have antioxidant properties. Free-radical damage plays a role in normal aging, and in such neurological conditions as epilepsy, Parkinson's disease, and Alzheimer's disease."

G. Dr. Val's Resveratrol: "Resveratrol may support heart health by providing the antioxidant protection needed for healthy circulation, and by inhibiting inflammation."

H. Dr. Val's Paracease: "Yet parasites are now considered to be the primary cause of occasional digestive disorders. The World Health Organization estimates that 3.5 billion people worldwide are infested with some type of intestinal parasite, and as many as 450 million of them are sick as a result Although parasites may not necessarily be the cause of a disease; they are extremely opportunistic and can make a disease worse."

I. Dr. Val's Oh My Back: "Oh My Back can help you live a pain-free life while improving mobility and flexibility."

J. The History of Aloe Vera: "Aloe Vera is filled with polysaccharides which are the naturally occurring active components that promote anti-inflammatory". "In 1944, the Japanese who were exposed to the "A" bomb applied aloe gel to their wounds and reported faster healing. Through the use of Aloe Vera, they also had significantly less scarring [sic] Ancient Chinese and Egyptians used Aloe Vera skin products to treat burns, wounds, and even reduce fevers."

K. What is Candida? "Candida Overgrowth (also known as Candida Overgrowth Syndrome or Candida Intestinal Overgrowth) involves bloating,

itching, rashes, and sugar/carb cravings. . . If left untreated, Systemic Candidiasis can occur compromising the Immune System..."

The above examples are not an exhaustive list of the claims made for the Defendants' dietary supplements, but are given as a representative sample.

18. TDSHS determined that different manufacturers were listed on the products' labels and that Defendants could not present evidence of a current manufacturing license for each of these manufacturers.

19. TDSHS determined that the label for Ultimate Protein Powder listed whey protein as an ingredient but failed to declare milk or soy as an allergen and stated that the product did not contain any milk or soy.

20. TDSHS determined that Defendants could not provide evidence that the Federal Food and Drug Administration had been notified of structure/function statements made for dietary supplements.

21. TDSHS determined that other labeling violations occurred on Defendants' products, including, but not limited to, the failure to include the term dietary supplement or other descriptive term as part of the statement of identity and the failure to list the manufacturer's address.

22. TDSHS determined that the FDA disclaimer statement on the website www.valeriesaxion.com was not in the correct format.

23. TDSHS determined that Defendant's products are labeled as a dietary supplement and the products do not meet the definition of a dietary supplement regarding ingestion, including but not limited to:

A. The product label for Alternative Health Labs Ultimate B-12 Supplement 100 Lozenges states "Suggested Usage: As a dietary supplement, take 1 lozenge 1 to 3 times per day....Chew lozenge or hold in mouth until dissolved."

B. Dr. Val's Special Formula Sublingual B12 Dietary Supplement is described on the label as "sublingual" on the primary display panel, and the Suggested Use directions state "As a dietary supplement, take 1 or 2 tablets....Allow tablets to dissolve under tongue."

24. TDSHS determined that Defendant's products are labeled as dietary supplements and they do not meet the definition of a dietary supplement, including but not limited to

A. The Alternative Health Labs Aloe's Secret Whole-Leaf Aloe Vera Drink Dietary Supplement product is labeled as a conventional food (drink) and a dietary supplement with a Supplement Facts panel. Additionally, the information panel on the product states "For both internal and external use."

B. The product label for Dr. Val's Special Formula Mineral Concentrate lacks "Dietary Supplement", "Mineral Supplement" or descriptive type of supplement as part of the statement of identity on its principal display panel.

25. TDSHS determined that Defendant makes nutrient content claims on their labels, website, and/or promotional materials for products that are distributed by their firm, but they do not meet the requirements to make the claim, including but not limited to:

A. The website states "Pomegranates are...They are a rich red fruit loaded with antioxidants, vitamins, potassium, folic acid, and iron." The product label for Alternative Health Labs PE Dietary Supplement does not list any vitamins,

potassium, folic acid, or iron in the Supplement Facts panel.

B. Alternative Health Labs PE Dietary Supplement product label states "High in Punicosides with Pomegranate Extract and Trans-Resveratrol."

C. The product label for Alternative Health Labs Ultimate Resveratrol states "Rich in Polyphenols!!" and Alternative Health Lab's Resveratrol contains a comprehensive blend of polyphenols, including natural Resveratrol and proanthocyanins (OPC's from grape seed), plus catechins (green tea extract).

VIOLATIONS OF THE TEXAS FOOD, DRUG, AND COSMETIC ACT

26. Based on the findings in paragraphs 16 through 25 above, incorporated herein by reference, Defendants have manufactured, held, offered for sale, distributed, sold, and/or introduced into commerce in Texas unapproved new drugs, misbranded drugs and foods, and falsely represented that these unapproved new drugs or misbranded foods could treat, mitigate, cure, or prevent various diseases. Defendants have also manufactured food within Texas without a food manufacturer's license.

27. Defendants manufacture, distribute, advertise, offer for sell, distribute, and/or sell products that are drugs within the meaning of §431.002(14) of the TFDCA because these products are intended to cure, mitigate, treat, or prevent disease.

28. Defendants manufacture, distribute, advertise, offer for sell, distribute, and/or sell products that are "new drugs" within the meaning of §431.002(25) of the TFDCA because the TDSHS is unaware of any evidence that establishes that Defendants' products are generally recognized as safe and effective for their intended uses.

29. Accordingly, the sale, delivery, offering for sale, holding for sale or giving away

of any new drugs without an FDA approved new drug application submitted by Defendants violates §431.114 (a)(1) of the TFDCa. The introduction or delivery for introduction into commerce of any article in violation of §431.114 of the TFDCa is prohibited under §431.021(e) of the TFDCa.

30. Defendants' drugs are misbranded under the terms of the TFDCa because their labeling fails to bear adequate directions for the uses for which these drugs are intended and being promoted in Texas. Section 431.112 (e)(1) of the TFDCa states that a drug is deemed to be misbranded unless its labeling bears adequate directions for use, unless the drug has been exempted from those requirements by regulations adopted by the Secretary of the United States Department of Health and Human Services.

31. By federal regulation, 21 CFR § 201.5, "[a]dequate directions for use means directions under which the layman can use a drug safely and for the purposes for which it is intended." The drugs promoted and sold by Defendants fail to bear adequate directions for their intended use as a drug since adequate directions for use cannot be written for the use of an unapproved drug by a layperson.

32. Defendants' products which are intended to cure, mitigate, treat, or prevent disease and/or whose labeling are not in conformance with state and federal standards are misbranded pursuant to §431.112(a) of the TFDCa because their labels are false and misleading.

33. Defendants' advertisements for unapproved new drugs are false by the terms of §431.183(a) of the TFDCa because they are directed toward the public and are not consistent with labeling claims permitted by the FDA or the approval process of FDA for drugs.

34. In the alternative, Defendants misbrand foods pursuant to §431.082(a),(t), and (u)

of the TFDCA by labeling their products as dietary supplements, which are foods under Texas law, and making claims to cure, treat, prevent or mitigate diseases for the foods.

35. Representations to cure, treat, prevent or mitigate diseases for misbranded foods or unapproved new drugs by Defendants constitute advertising within the definition set out in §431.002(1) of the TFDCA since they are intended to induce consumers to purchase Defendants' drugs or foods.

36. Defendants' promotion of misbranded foods or unapproved new drugs is false within the meaning of §431.182 of the TFDCA because it is misleading in numerous particulars as set out above.

37. The labels for Defendants' dietary supplements which fail to include the term dietary supplement or other descriptive term as part of the statement of identity, fail to list the manufacturer's address, or fail to declare allergens misbrand Defendants' dietary supplements under §431.082(a), (f), and/or (g) of the TFDCA.

PROHIBITED ACTS UNDER THE TEXAS FOOD, DRUG AND COSMETIC ACT

38. Based on the conduct alleged above in paragraphs 1 through 37, Defendants have committed or caused to be committed the following acts prohibited and declared to be unlawful by §431.001 *et seq.* of the TFDCA:

- a. Introducing unapproved new drugs into commerce in violation of § 431.021(e) of the TFDCA;
- b. Introducing into commerce a misbranded drug by manufacturing, advertising, offering to sell, and selling a drug that does not have adequate directions for use, in violation of §431.021(a) of the TFDCA;

- c. Misbranding drugs and food in commerce in violation of §431.021(b) of the TFDCA;
- d. Introducing into commerce a misbranded food, including a dietary supplement, by manufacturing, advertising, offering to sell, and selling such food that makes claims to cure, treat, prevent, or mitigate disease, in violation of §431.021(a) of the TFDCA;
- e. Introducing into commerce a misbranded food, including a dietary supplement, by manufacturing, advertising, offering to sell, and selling such food that fails to comply with federal and state labeling requirements, in violation of §431.021(a) of the TFDCA;
- f. Falsely advertising or falsely representing that a drug or food, including a dietary supplement, is effective for treating diseases of the body, such as cancer, when FDA has not approved these drugs, in violation of §431.021(f) of the TFDCA;
- g. Manufacturing within Texas of any food or drug that is misbranded, in violation of §431.021(h); and
- h. Engaging in the manufacture of food in this state without having a license in violation of §431.021(y).

VIOLATIONS OF THE TEXAS DECEPTIVE TRADE PRACTICES ACT

39. Defendants as alleged above in paragraphs 1 through 38, have in the course of trade and commerce engaged in false, misleading and deceptive acts and practices declared unlawful in §17.46(a). Additionally, Defendants have violated §17.46(b) of the DTPA as follows:

- a. Causing confusion or misunderstanding as to the approval of the drugs or foods, including dietary supplements, manufactured by Defendants, in violation of §17.46(b)(2) of the DTPA;
- b. Representing that Defendants' drugs or foods, including dietary supplements, have sponsorship, approval, characteristics, uses, or benefits which they do not have, in violation of §17.46(b)(5) of the DTPA;
- c. Representing that Defendants' drugs or foods, including dietary supplements, are of a particular standard, quality, or grade, if they are of another, in violation of §17.46(b)(7) of the DTPA;
- d. Failing to disclose that claims to diagnose, mitigate, treat, cure, or prevent disease cannot legally be made for dietary supplements, when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of §17.46(b)(24) of the DTPA; and
- e. Representing that VALERIE SAXION has approval, status, affiliation, or connection when she does not, in violation of §17.46(b)(5) of the DTPA.

INJURY TO CONSUMERS UNDER THE DTPA

40. By means of the foregoing unlawful acts and practices, Defendants have acquired money or other property from consumers, as that term is defined in §17.44(4) of the DTPA.

REQUEST FOR INJUNCTION

41. Defendants have violated and could continue to violate the laws of Texas as hereinabove alleged. Defendants VALERIE SAXION, INC. and VALERIE SAXION,

individually, unless restrained by this Honorable Court for past violations and the threat of continuing violations of the TFDCA and the DTPA could continue to violate the laws of Texas.

PRAAYER

42. WHEREFORE, PREMISES CONSIDERED, the STATE OF TEXAS prays that Defendants VALERIE SAXION, INC. and VALERIE SAXION, individually, be cited according to law to appear and answer herein; that after due notice and hearing a temporary injunction be issued and, upon final hearing, a permanent injunction be issued restraining and enjoining Defendants individually and by their agents, servants, employees, and representatives from making the representations, doing the acts, and engaging in the practices set out in the preceding paragraphs as well as from making the following representations and doing the following acts and engaging in the following practices in the pursuit and conduct of trade or commerce within the State of Texas as follows:

- a. Introducing and delivering into commerce misbranded drugs or food;
- b. The misbranding of any drugs or food in commerce;
- c. Selling or offering to sell any unapproved new drug;
- d. Representing that goods are of a particular standard, quality, or grade if they are of another by making claims, either explicitly or implicitly, that dietary supplements can diagnose, mitigate, treat, cure, or prevent disease;
- e. Failing to disclose that claims to diagnose, mitigate, treat, cure, or prevent disease cannot legally be made for dietary supplements;
- f. Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have by making claims, either explicitly or implicitly, to diagnose, mitigate, treat, cure, or prevent disease for dietary supplements.
- g. Representing that a person has a sponsorship, approval, status, affiliation, or

connection which she does not have by using the title "Doctor," or the abbreviation "Dr." in connection with Valerie Saxion;

- h. Representing that a person has a sponsorship, approval, status, affiliation, or connection which she does not have and that goods have sponsorship or approval which they do not have by using the title "Dr. Val's" on the labels of any of their products;
- i. Representing that a person has a sponsorship, approval, status, affiliation, or connection which she does not have by using the title, "Doctor of Naturopathy," or "N. D." in Texas in connection with Valerie Saxion;
- j. Making claims, either explicitly or implicitly, to diagnose, mitigate, treat, cure, or prevent disease for dietary supplements through any means, including, but not limited to, websites, product labels and brochures, catalogs, television programs or advertisements, radio programs or advertisements; third party vendors; and third party websites;
- k. Manufacturing food in Texas without a license for each manufacturer listed on the product labels;
- l. Failing to comply with the labeling requirements for dietary supplements, including, but not limited to, failing to include the term dietary supplement or other descriptive term as part of the statement of identity, failing to list the manufacturer's address, and failing to declare allergens;
- m. Failing to notify the Federal Food and Drug Administration of structure/function statements for each of the dietary supplements containing such statements;
- n. Manufacturing misbranded food or drugs;
- o. Using any testimonial to make a claim that dietary supplements diagnose, mitigate, treat, cure, or prevent disease;
- p. Represent that any research, study, or publication supports a claim that any of Defendants' products, or any ingredient in any of Defendants' products, can cure, treat, mitigate, or prevent any disease;
- q. Disseminating any false advertisements or causing the dissemination of false advertising;
- r. Failing to provide written notice to any agent, servant, employee, or representative of the existence and terms of any injunction entered in this case, and of their duty.

to comply with the terms set forth herein;

- s. Failing to provide written notice to any person or entity who promotes, advertises and/or sells Defendants' products of the existence and terms of any injunction entered in this case, and of their duty to comply with the terms set forth herein;
- t. Using any internet search parameters, such as metatags, search and source codes, to link those searching for detrimental health conditions, diseases, or disease treatments to Defendants' website(s);
- u. Representing that their business is approved by the Texas Department of State Health Services or is in compliance with the Texas Department of State Health Services' policies and procedures; and
- v. Representing that their business is approved by the Office of the Attorney General.

43. The STATE OF TEXAS further prays that upon final hearing this Court order Defendants VALERIE SAXION, INC. and VALERIE SAXION, individually, to pay civil penalties to the State of Texas up to \$25,000 per violation per day for each violation of §431.021 of the TFDCA, as provided in §431.0585(b) of the TFDCA.

44. The STATE OF TEXAS further prays that upon final hearing this Court order Defendants VALERIE SAXION, INC. and VALERIE SAXION, individually, to pay civil penalties to the State of Texas of up to \$20,000 for each violation of the DTPA, pursuant to TEX. BUS. & COM. CODE ANN. § 17.47(c)(1).

45. The STATE OF TEXAS further prays that the Office of the Attorney General and the Commissioner of Health be awarded their investigative costs, court costs, reasonable attorneys' fees, expenses, and witness fees pursuant to the laws of the State of Texas including, but not limited to, TEX. HEALTH & SAFETY CODE ANN. §431.047(d) and TEX. GOV'T CODE ANN. §402.006(c).

46. The STATE OF TEXAS further prays that this Court grant all other relief to which the State of Texas is justly entitled.

Respectfully Submitted,

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